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PATENT

ATTORNEY DOCKET NO. PRES06-00163
Customer No. 23990

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of : Ronald A. Schachar
U.S. Serial No. : 09/556,143
Filing Date : April 21, 2000
Examiner : David M. Shay
Group Art Unit : 3735
Title : SEGMENTED SCLERAL BAND FOR TREATMENT OF
PRESBYOPIA AND OTHER EYE DISORDERS
Confirmation No. : 6710

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Commissioner for Patents
P.O. Box 1450
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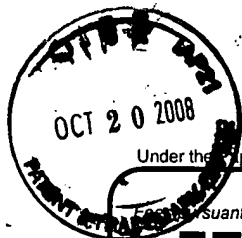
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FEE TRANSMITTAL

For FY 2009

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 540.00

Complete if Known

Application Number	09/556,143
Filing Date	April 21, 2000
First Named Inventor	Ronald A. Schachar
Examiner Name	David M. Shay
Art Unit	3735
Attorney Docket No.	PRES06-00163

METHOD OF PAYMENT (check all that apply)☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____☒ Deposit Account Deposit Account Number: 50-0208 Deposit Account Name: Munck Carter, P.C.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17☒ Credit any overpayments**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	330	165	540	270	220	110	
Design	220	110	100	50	140	70	
Plant	220	110	330	165	170	85	
Reissue	330	165	540	270	650	325	
Provisional	220	110	0	0	0	0	

2. EXCESS CLAIM FEES**Fee Description**

Each claim over 20 (including Reissues)

Fee (\$)	Small Entity Fee (\$)
52	26

Each independent claim over 3 (including Reissues)

220	110
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Multiple dependent claims

390	195
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Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
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- 20 or HP = _____ x _____ = _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
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- 3 or HP = _____ x _____ = _____

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$270 (\$135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
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4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Fees Paid (\$)

Other (e.g., late filing surcharge): Appeal Brief filing fee

540.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 38,309	Telephone 972-628-3600
Name (Print/Type)	William A. Munck		Date October 16, 2008

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MAIL STOP APPEAL BRIEF - PATENTS

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APPEAL BRIEF

The Appellant has appealed to the Board of Patent Appeals and Interferences from the decision of the Examiner dated January 8, 2008, finally rejecting Claims 40-59. The Appellant filed a Notice of Appeal and a Pre-Appeal Brief Request for Review on July 8, 2008. A Notice of Panel Decision from Pre-Appeal Brief Review was mailed on September 17, 2008 and set at least a one-month period for filing this Appeal Brief. As a result, this Appeal Brief is being timely submitted by October 17, 2008.

The Appellant respectfully submits this brief on appeal.

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Real Party in Interest

This application is currently owned by Refocus Ocular, Inc. as indicated by:

(1) an assignment recorded on January 21, 2005 in the Assignment Records of the United States Patent and Trademark Office at Reel 015612, Frame 0457;

(2) a merger recorded on January 21, 2005 in the Assignment Records of the United States Patent and Trademark Office at Reel 015612, Frame 0466; and

(3) a change of name recorded on January 21, 2005 in the Assignment Records of the United States Patent and Trademark Office at Reel 015612, Frame 0469.

Related Appeals or Interferences

The appeal for this patent application is related to appeals involving the following patent applications:

- U.S. Patent Application No. 11/322,728 filed on December 30, 2005; and
- U.S. Patent Application No. 11/323,752 filed on December 30, 2005.

Notices of appeal have been filed in both of these related patent applications. All three patent applications involve similar issues on appeal.

Status of Claims

Claims 1-39 have been cancelled. Claims 40-59 have been rejected pursuant to a final Office Action dated January 8, 2008. Claims 40-59 are presented for appeal. A copy of Claims 40-59 is provided in Appendix A.

Status of Amendments after Final

No amendments were filed after issuance of the final Office Action on January 8, 2008.

SUMMARY OF CLAIMED SUBJECT MATTER

The following summary refers to disclosed embodiments and their advantages but does not delimit any of the claimed inventions.

In General

The present application is directed, in general, to treating presbyopia and other eye disorders. (04/21/00 *Substitute Specification*, Page 6, Lines 2-4). Presbyopia refers to the inability to focus on near objects, which typically occurs in people over 40 years of age. (04/21/00 *Substitute Specification*, Page 4, Lines 2-7). Presbyopia and other eye disorders can be treated by irradiating the sclera of the eye in the region of the ciliary body of the eye. (04/21/00 *Substitute Specification*, Page 20, Line 18 – Page 21, Line 1). The sclera represents the white outer supporting structure of the eye, and the ciliary body represents a muscular ring located just within the sclera that pulls on the lens of the eye to change the eye's focus. (04/21/00 *Substitute Specification*, Page 2, Line 15 – Page 3, Line 20). This irradiation weakens the sclera of the eye in the region of the ciliary body. (04/21/00 *Substitute Specification*, Page 20, Lines 18-19).

The weakening of the sclera causes a portion of the sclera to bulge outward, thereby increasing the diameter of the ciliary body. (04/21/00 *Substitute Specification*, Page 19, Line 22 – Page 20, Line 3). The increase in the diameter of the ciliary body helps to increase the effective working distance of the ciliary muscle of the eye, which can help to restore the ability

of the ciliary muscle to exert force on the lens of the eye and to change the shape of the lens. (04/21/00 Substitute Specification, Page 12, Lines 7-14). Among other things, this can help to reduce or eliminate presbyopia. (04/21/00 Substitute Specification, Page 12, Lines 3-6).

An opening need not be formed completely through the sclera of the eye. Rather, the sclera can be weakened by “thinning” the sclera, such as by removing a “portion of the thickness” of the sclera using a laser. (04/21/00 Substitute Specification, Page 20, Line 20 – Page 21, Line 1).

Support for Independent Claims

Note that, per 37 C.F.R. § 41.37, only the independent claims are discussed in this section. The discussion of the claims in this section is for illustrative purposes and is not intended to affect the scope of the claims.

Regarding Claim 40, a method of operating a laser to treat presbyopia, hyperopia, primary open angle glaucoma or ocular hypertension is provided. (04/21/00 Substitute Specification, Page 1, Lines 3-6; Page 20, Line 18 – Page 21, Line 1). The method includes irradiating a sclera of an eye in a region of a ciliary body to thereby weaken the sclera of the eye and increase an effective working distance of a ciliary muscle of the eye. (04/21/00 Substitute Specification, Page 20, Line 18 – Page 21, Line 1; Page 19, Line 22 – Page 20, Line 3). Irradiating the sclera includes reducing a thickness of the sclera in the region of the ciliary body without forming an opening completely through the sclera. (04/21/00 Substitute Specification, Page 20, Line 20 – Page 21, Line 1).

Regarding Claim 47, a method includes irradiating a sclera of an eye in a region of a ciliary body of the eye to increase an effective working distance of a ciliary muscle of the eye. (04/21/00 *Substitute Specification*, Page 20, Line 18 – Page 21, Line 1; Page 19, Line 22 – Page 20, Line 3). Irradiating the sclera includes reducing a thickness of the sclera in the region of the ciliary body without forming an opening completely through the sclera. (04/21/00 *Substitute Specification*, Page 20, Line 20 – Page 21, Line 1).

Regarding Claim 54, a method includes providing a laser operable to irradiate a sclera of an eye in a region of a ciliary body of the eye and operating the laser to irradiate the sclera in the region of the ciliary body to increase an effective working distance of a ciliary muscle of the eye. (04/21/00 *Substitute Specification*, Page 1, Lines 3-6; Page 20, Line 18 – Page 21, Line 1). Operating the laser to irradiate the sclera in the region of the ciliary body includes reducing a thickness of the sclera in the region of the ciliary body without forming an opening completely through the sclera. (04/21/00 *Substitute Specification*, Page 20, Line 20 – Page 21, Line 1).

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Are Claims 40-59 anticipated under 35 U.S.C. § 102(b) by March et al., “Safety of High-Energy Neodymium:YAG Laser Pulses in YAG Sclerostomy” (“*March*”)?

ARGUMENT

Stated Grounds of Rejection

Claims 40-59 stand rejected under 35 U.S.C. § 102(b) as being anticipated by March et al., “Safety of High-Energy Neodymium:YAG Laser Pulses in YAG Sclerostomy” (“*March*”).

Legal Standards

A prior art reference anticipates a claimed invention under 35 U.S.C. § 102 only if every element of the claimed invention is identically shown in that single reference, arranged as they are in the claims. (MPEP § 2131; *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990)). Anticipation is only shown where each and every limitation of the claimed invention is found in a single prior art reference. (MPEP § 2131; *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985)).

To establish inherency, the burden is on the Examiner to present evidence clearly showing that “the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” (*MPEP* § 2112). However, the fact that a “certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” (*MPEP* § 2112). The Examiner must “provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows” from the teachings of cited reference. (*MPEP* § 2112). Moreover, according to a recent BPAI decision, a rejection

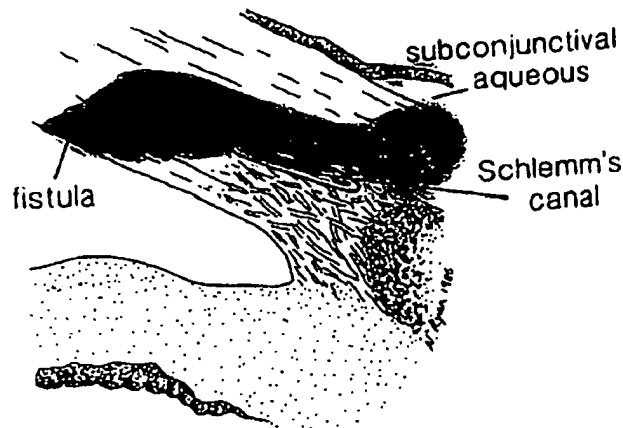
based on inherency cannot be maintained when an Examiner fails to provide “evidence or scientific reasoning” to show that a cited reference disclosed elements of a claimed invention. (*Ex parte Whalen II*; issued July 23, 2008; slip opinion, page 12).

Analysis of Examiner's Rejections

The cited reference is briefly discussed in relevant part, and the rejection of the claims is addressed below.

Ground of Rejection 1: Claims 40-59 stand rejected under 35 U.S.C. § 102(b) as being anticipated by March et al., “Safety of High-Energy Neodymium:YAG Laser Pulses in YAG Sclerostomy” (“March”)

March recites a technique for using laser pulses to form a “new channel for drainage of aqueous humor” in an eye to treat glaucoma. (*March*, Page 584, Left column, Introduction). Figure 6 in *March*, which is reproduced below, indicates that the new channel (called a fistula) is formed completely through the sclera of the eye. (*March*, Page 587, Left column, Figure 6).



This fistula helps to lower intraocular pressure by allowing aqueous humor to drain from the interior of the eye, thereby helping to treat glaucoma. (*March*, Page 584, Left column, Introduction; Page 586, Left and right columns). This new technique is an improvement over “previous laser treatments” that failed to create a “complete scleral perforation.” (*March*, Page 586, Right column). The laser used in *March* is a pulsed Neodymium:YAG laser with 12-nanosecond pulses at 130-135 millijoules. (*March*, Page 584, Right column).

CLAIMS 40-59

Claim 40 recites a method of operating a laser to treat presbyopia, hyperopia, primary open angle glaucoma or ocular hypertension that includes:

irradiating a sclera of an eye in a region of a ciliary body to thereby weaken the sclera of the eye and increase an effective working distance of a ciliary muscle of the eye;
wherein irradiating the sclera comprises reducing a thickness of the sclera in the region of the ciliary body without forming an opening completely through the sclera.

Claim 40 therefore recites that (i) the sclera of an eye is irradiated in a particular area to “weaken the sclera of the eye and increase an effective working distance of a ciliary muscle of the eye” and (ii) this is done “without forming an opening completely through the sclera.”

March clearly notes that the goal of its new treatment is to form a “complete scleral perforation,” or an opening completely through the sclera. As a result, the new technique disclosed in *March*, performed to completion, cannot possibly anticipate Claim 40.

Instead, the Examiner can rely on only two other teachings in *March* as anticipating

Claim 40:

(1) the “previous laser treatments” that failed to produce a complete scleral perforation;
and

(2) the time between pulses during the new treatment of *March* (meaning the time when the complete scleral perforation is being formed during, but before completion of, the new treatment in *March*).

Regarding (1), the Examiner has never shown that the “previous laser treatments” in *March* involved irradiating a region of an eye to “increase an effective working distance of a ciliary muscle of the eye.” While the “previous laser treatments” in *March* failed to form a complete scleral perforation, *March* never actually describes those “previous laser treatments.” *March* never discloses the exact locations of laser irradiation in the previous laser treatments, the amount of tissue removed during those previous laser treatments, or any other details of those previous laser treatments. The Examiner cannot establish that this discussion in *March* inherently anticipates “irradiating a sclera of an eye ... to thereby weaken the sclera of the eye and increase an effective working distance of a ciliary muscle of the eye.” Nothing in *March* indicates that an adequate amount of tissue is removed to weaken the sclera or increase the ciliary muscle’s effective working distance.

Regarding (2), the new treatment of *March* involves using a pulsed laser. Between laser pulses during the new treatment of *March*, a complete scleral perforation has not yet been formed in the eye. However, the Examiner cannot possibly establish that, for the brief period between the start of laser treatment and the complete formation of a scleral perforation, *March*

inherently anticipates “irradiating a sclera of an eye ... to thereby weaken the sclera of the eye and increase an effective working distance of a ciliary muscle of the eye.” The Examiner has never even attempted to show that an adequate amount of tissue is removed during the new treatment of *March* to weaken the sclera or increase the ciliary muscle’s effective working distance during this brief period of time.

The Examiner cannot show that *March* explicitly discloses all elements of Claim 40. Instead, the Examiner asserts that various elements of Claim 40 are inherent in *March*. However, the Examiner’s arguments regarding inherency are merely assumptions without any evidence whatsoever.

In the December 15, 2006 Office Action, the Examiner states that he “must rely upon the laws of physics as they are currently understood and presume that removal of the substance of a structure will leave that structure weaker than before removal.” (12/15/06 Office Action, Page 3, Last paragraph). The Examiner then assumes that since *March* inherently weakens the eye, this would inherently lead to expansion of the sclera and an increase in the effective working distance of the ciliary muscle. (12/15/06 Office Action, Page 3, Last paragraph).

The Examiner never identifies the alleged “laws of physics” that state that the removal of any amount of scleral tissue from an eye in any way weakens the sclera and leads to scleral expansion. Moreover, the Examiner’s use of the term “presume” here is notable – presumptions are inadequate to establish inherency. Instead, the MPEP clearly specifies that inherency cannot be established by mere “probabilities” or “possibilities.” (MPEP § 2112). The Examiner’s creation of a law of physics and the Examiner’s presumption that this law applies to *March* is

inadequate to prove inherency.

In the Advisory Action dated March 13, 2007, the Examiner argues that “pressure changes with every beat of the heart, which ... changes the fluid pressure of the eye” and that the claims “make no reference to the changing pressure in the[] eye.” (03/13/07 *Advisory Action*, Page 2). The exact relevance of this discussion is unknown since the Examiner never explained why changing pressure in the eye would make certain teachings inherent in *March*.

In the January 8, 2008 Office Action, the Examiner refers to the “exhaustive treatment” of the inherency issue in the December 15, 2006 Office Action and the March 13, 2007 Advisory Action. (01/08/08 *Office Action*, Page 3, *Last paragraph*). As noted above, however, this “exhaustive treatment” involves the creation of a physical law, the presumption that the physical law applies to *March*, and a discussion about changing eye pressure that is not relevant.

In the Advisory Action dated June 25, 2008, the Examiner declares that the law of physics created in the earlier Office Action is an “undeniable fact.” (06/25/08 *Advisory Action*, Page 2). The Examiner also argues that “were the reverse true, structures made of no material at all would be as strong or stronger as a structure which did contain material.” (06/25/08 *Advisory Action*, Page 2). However, the Examiner has never established any “undeniable fact” stating that “any material removed from any structure in any way weakens the structure.” More importantly, the Examiner has never established that “any material removed from any part of an eye in any way weakens the eye and allows scleral expansion and an increase in the ciliary muscle’s effective working distance.” Also, the Examiner’s statement that “structures made of no material at all would be as strong or stronger as a structure which did contain material” is clearly a

strawman argument – the Examiner is making a rather ridiculous proposition (not asserted by the Appellant) and then arguing against it as proof of his own inherency argument.

The Examiner here appears to believe that the claims can be rejected as being anticipated as long as any reference discloses any removal of scleral tissue in the region of the ciliary body and no complete opening is formed for any length of time. This is obviously the incorrect standard. The *Ex parte Whalen II* decision clearly notes that the standard for inherency is evidence or scientific reasoning, not mere speculation on what might occur. The Examiner needs to present actual proof (not mere “probabilities or possibilities”) that the removal of tissue as specifically disclosed in *March* actually weakens the sclera and allows an increase in the ciliary muscle’s effective working distance. The Examiner has not made this showing as specifically required by MPEP § 2112 and *Ex parte Whalen II*. Instead, the Examiner has merely made presumptions and assumptions in rejecting the claims.

In addition, the Examiner improperly places the burden of disproving inherency on the Appellant, rather than placing the burden of proving inherency on the Office. The Examiner has never shown that *March* removes an adequate amount of tissue to weaken the sclera of an eye and increase the ciliary muscle’s effective working distance. The Examiner has simply assumed that *March* removes adequate tissue, assumed that this would weaken the sclera, and assumed that this would allow an increase in the effective working distance of the ciliary muscle. The Examiner has then left it up to the Appellant to disprove this series of assumption. However, MPEP § 2112 places the burden of proving inherency on the Examiner, and the Examiner has not met this burden.

March is crystal clear – a complete scleral perforation is formed through the sclera of an eye. That much is clear on the face of *March*, but this portion of *March* cannot anticipate Claim 40 since Claim 40 specifically prohibits the formation of an opening completely through the sclera. What occurs during the “previous laser treatments” mentioned in *March* and what occurs between laser pulses in the new treatment of *March* are unclear, but the law places the burden of establishing inherency on the Examiner. The Examiner has not and cannot establish that scleral weakening and scleral expansion occur during the “previous laser treatments” mentioned in *March* or between laser pulses during the new treatment of *March*. Without actual evidence that *March* weakens the sclera and allows scleral expansion, the Examiner cannot show that *March* inherently anticipates Claim 40.

For these reasons, *March* fails to anticipate the Appellant’s invention as recited in Claim 40 (and its dependent claims). For similar reasons, *March* fails to anticipate the Appellant’s invention as recited in Claims 47 and 54 (and their dependent claims).

Accordingly, the Appellant respectfully requests that the § 102 rejection of Claims 40-59 be withdrawn and that Claims 40-59 be passed to allowance.

REQUESTED RELIEF

The Board is respectfully requested to reverse the outstanding rejections and return this application to the Examiner for allowance.

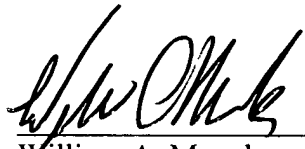
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Respectfully submitted,

MUNCK CARTER, P.C.

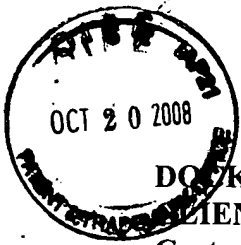
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Examiner: David M. Shay

Art Group Unit: 3735

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APPENDIX A -
Claims Appendix

1.-39. (Cancelled).

40. A method of operating a laser to treat one of: presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension, said method comprising the step of:

irradiating a sclera of an eye in a region of a ciliary body to thereby weaken the sclera of the eye and increase an effective working distance of a ciliary muscle of the eye;

wherein irradiating the sclera comprises reducing a thickness of the sclera in the region of the ciliary body without forming an opening completely through the sclera.

41. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of abrading the sclera with laser irradiation.

42. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of ablating the sclera with laser irradiation.

43. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of incising the sclera with laser irradiation.

44. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of decomposing partially collagen fibers in the sclera.

45. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of incising at least a portion of the sclera at select angles with laser irradiation.

46. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises increasing a diameter of the sclera overlying the ciliary body.

47. A method, comprising:
irradiating a sclera of an eye in a region of a ciliary body of the eye to increase an effective working distance of a ciliary muscle of the eye;
wherein irradiating the sclera comprises reducing a thickness of the sclera in the region of the ciliary body without forming an opening completely through the sclera.

48. The method of Claim 47, wherein irradiating the sclera comprises abrading the sclera with laser irradiation.

49. The method of Claim 47, wherein irradiating the sclera comprises ablating the sclera with laser irradiation.

50. The method of Claim 47, wherein irradiating the sclera comprises incising the sclera with laser irradiation.

51. The method of Claim 47, wherein irradiating the sclera comprises incising at least a portion of the sclera at select angles with laser irradiation.

52. The method of Claim 47, wherein irradiating the sclera comprises decomposing partially collagen fibers in the sclera.

53. The method of Claim 47, wherein irradiating the sclera comprises increasing a diameter of the sclera overlying the ciliary body.

54. A method, comprising:
- providing a laser operable to irradiate a sclera of an eye in a region of a ciliary body of the eye; and
- operating the laser to irradiate the sclera in the region of the ciliary body to increase an effective working distance of a ciliary muscle of the eye;
- wherein operating the laser to irradiate the sclera in the region of the ciliary body comprises reducing a thickness of the sclera in the region of the ciliary body without forming an opening completely through the sclera.
55. The method of Claim 54, wherein the laser is operable to abrade the sclera.
56. The method of Claim 54, wherein the laser is operable to ablate the sclera.
57. The method of Claim 54, wherein the laser is operable to incise the sclera.
58. The method of Claim 54, wherein the laser is operable to incise at least a portion of the sclera at select angles with laser irradiation.

59. The method of Claim 54, wherein the laser comprises at least one of: a carbon dioxide laser, a helium-neon laser, a helium-cadmium laser, an argon ion laser, a krypton ion laser, a xenon laser, a nitrous oxide laser, an iodine laser, a holmium doped yttrium-aluminum garnet (YAG) laser, an excimer laser, a chemical laser, a harmonically oscillated laser, a dye laser, a nitrogen laser, a neodymium laser, an erbium laser, a ruby laser, a titanium-sapphire laser, and a diode laser.

DOCKET NO. PRES06-00163

PATENT

CLIENT NO. PRES06-00163

Customer No. 23990



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ronald A. Schachar

Serial No.:

09/556,143

Filed:

April 21, 2000

Title:

SEGMENTED SCLERAL BAND FOR TREATMENT OF
PRESBYOPIA AND OTHER EYE DISORDERS

Examiner:

David M. Shay

Art Group Unit:

3735

Confirmation No.:

6710

APPENDIX B
Evidence Appendix

None.

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APPENDIX C
Related Proceedings Appendix

None – no decisions have been entered in any of the related applications identified above.